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COOPER & DUNHAM, LLP			CONWAY, THOMAS A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,666	Applicant(s) SHIRAHATA ET AL.
	Examiner THOMAS A. CONWAY	Art Unit 4182

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01/27/2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 January 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-166/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/27/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

It would be of great assistance to the Office if all incoming papers pertaining to a filed application carried the following items:

1. Application number (checked for accuracy, including series code and serial no.).
2. Group art unit number (copied from most recent Office communication).
3. Filing date.
4. Name of the examiner who prepared the most recent Office action.
5. Title of invention.
6. Confirmation number (See MPEP § 503).

Specification

1. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

2. The abstract of the disclosure is objected to because the abstract in the instant application exceeds the maximum one paragraph limit. Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informality: the instant application recites "...viscera extracting unit 150 ... and main memory 14" (Page 22, paragraph [0030]), with reference to fig. 15. Fig. 15 does not show the connection between 150 and the keyboard (19). The language seems to point to a direct physical connection.

4. The disclosure is objected to because of the following informality: the instant application recites "... setting unit 151 ... viscera extracting unit 150", with reference to fig. 15 (Page 22, paragraph [0030]). Fig. 15 does not show the connection between 151, the mouse and the main memory. The language seems to point to a direct physical connection.

5. The disclosure is objected to because of the following informality: the instant application on page 54, line 3, recites "ROI500". It is assumed that this should read as "ROI 500", with reference to fig. 33.

Appropriate correction is required.

Drawings

6. The drawings are objected to because the figure 14 is mentioned initially in the drawing list but is not further developed in the disclosure and the associated numbered elements (140-144). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 recites the limitation "for storing the index of the deformation degree" on line 8. Claim 1 recites the limitation "the examiner" on line 17.
8. Claim 2 recites the limitation "the bifurcation" on page 2, line 1. Claim 2 recites the limitation "the plurality or the cross-sections" on page 2, line 3. Claim 2 recites the limitation "the shortest distance of the opposed peripheral portion" on page 2, lines 6-7.
9. Claim 3 recites the limitation "the plurality of templates" on lines 2-3.
10. Claim 4 recites the limitation "the lumen" on page 3, line 2.
11. Claim 5 recites the limitation "the hollow viscera" on line 4. Claim 5 recites the limitation "the cross-sectional images of the hollow viscera" on lines 9-10.

12. Claim 6 recites the limitation "the display images" on line 4.
13. Claim 7 recites the limitation "the lesion candidate points" on line 5.
14. Claim 8 recites the limitation "the variance" on line 4.
15. Claim 9 recites the limitation "the feature quantity of the hollow viscera" on line 4.
Claim 9 recites the limitation "the radius" on page 5, line 3.

There is insufficient antecedent basis for the limitations in these claims. There are similar issues with claims 11-19, correction of claims 1-9 as laid out above will be sufficient to address the problems with claims 11-19, with regards to antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6, 11, 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Giger et al. (U.S. Pub. No.: 2001/0043729 A1, "Giger").

16. **Regarding claims 1 and 11,** Giger discloses a medical image diagnosis support device (claim 36), comprising:

an organ region setting means for setting the organ regions from the medical images of the subject being obtained by a medical imaging device (claim 1, line 3);

a deformation calculating means for calculating the deformation degree of the organ regions being set by the organ region setting means (claim 1, lines 9-12);

a reference value storing means for storing the index of the deformation degree of the organ region as a reference value (claim 1, lines 6-8);

a lesion detecting means for detecting the existence of the lesion of the organ region from the result of comparing the reference value being stored by the reference value storing means with the deformation degree being calculated by the deformation degree calculating means (claim 1, lines 6-7); and

a presenting means for presenting the existence of the lesions of the organ region being detected by the detecting means to the examiner visually (claim 1, lines 13-14).

17. **Regarding claims 3 and 13,** Giger discloses a medical image diagnosis support device, wherein the reference value storing means stores the plurality of templates according to the deformation degree of the organ region (paragraph [0011], lines 7-9).

18. **Regarding claims 6 and 16,** Giger discloses a medical image diagnosis support device, wherein the presenting means presents the existence of a lesion to the examiner visually by displaying it through colors or movement in the display images (claim 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 4, 5, 7, 9, 12, 14, 15, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger, in view of Greenberg et al. (US 6,301,498 B1: "Greenberg").

19. **Regarding claims 2 and 12,** while Giger discloses the limitations of claims 1 and 11, Giger fails to disclose the limitations of claims 2 and 12.

Greenberg discloses the means of detecting the bifurcation of the previously calculated organ region (Col. 10, lines 17-21); a means for creating the plurality of the cross-sections of the organ region being diverged by the bifurcation being detected by the detecting means (Fig. 6d); and a distance calculating means for calculating the shortest distance of the opposed peripheral portion between each of the plurality of

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cross-sectional images being created (Col. 2, lines 36-42), and wherein the lesion detecting means detects the existence of a lesion in the organ region based on the shortest distance of the opposed peripheral portion between the plurality of the cross-sectional images being calculated by the distance calculating means (Col. 3, lines 45-47).

Giger's disclosure was detailed with specific reference to mammographic details but as he mention in paragraph [0070], the elements of his invention can be implemented for other medical images, such as chest radiography, ultrasound, and magnetic resonance imaging. Acknowledgement that these other types of imaging is acceptable, suggests that the details of that imaging could encompass terms or structures not explicitly mentioned in the Giger patent, such as, "organ", "bifurcation", "viscera" and "lumen".

Since examination of internal organs and other localized structures are available as per Giger's disclosure, then the examination of these would be specific to their featured characteristics (See Giger, claim 1). Since lesions, stenosis and the like are often characterized by constriction or narrowing of a structure under inspection (specific to Greenberg's examination of arteries), examination of the geometric attributes of the suspect region would be an obvious endeavor (Greenberg, Col. 3, lines 18-25). Giger doesn't specifically mention using cross-sectional images since his invention was dealing with mammography, but examination of other internal organs was known in the art at the time of the invention, to frequently deal with cross-sectional images or "slices".

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to include in the method as outlined by Giger, the means as outlined by Greenberg, for detecting the bifurcation of the previously calculated organ region; a means for creating the plurality of the cross-sections of the organ region being diverged by the bifurcation being detected by the detecting means; and a distance calculating means for calculating the shortest distance of the opposed peripheral portion between each of the plurality of cross-sectional images being created, and wherein the lesion detecting means detects the existence of a lesion in the organ region based on the shortest distance of the opposed peripheral portion between the plurality of the cross-sectional images being calculated by the distance calculating means, in order to examine other internal structures other than mammarys.

20. **Regarding claims 4 and 14,** while Giger fails to disclose their limitations, Greenberg does disclose a cross-sectional image calculating means for calculating the cross-sectional images that are orthogonal to axial direction of the organ region (Fig. 5A); and an extracting means for extracting the lumen and the exterior of the organ region from the cross-sectional images being calculated from the cross-sectional image calculating means (Fig. 5E); and calculates the degree of deformation of the lumen and the exterior of the organ region being extracted by the extracting means (Col. 8, lines 40-54)

Therefore, for the same reasons as stated in the presentation of claims 2 and 12 (see above), it would have been obvious to one of ordinary skill in the art at the time the

invention was made, to include in the method as outlined by Giger, the means as outlined by Greenberg, for calculating the cross-sectional images that are orthogonal to axial direction of the organ region; and an extracting means for extracting the lumen and the exterior of the organ region from the cross-sectional images being calculated from the cross-sectional image calculating means; and calculates the degree of deformation of the lumen and the exterior of the organ region being extracted by the extracting means, in order to examine other internal structures other than mammarys.

21. **Regarding claims 5 and 15,** while Giger discloses the limitations of claims 1 and 11, upon which claims 5 and 15 are dependent, Giger fails to disclose the limitations of claims 5 and 15.

Greenberg discloses a means for extracting the hollow viscera out of the organ region being set by the organ region setting means (Col. 5, lines 11-30); a notable region setting means for setting the notable region of the hollow viscera being extracted by the extracting means (Col. 9, lines 19-24); and a means for creating the cross-sectional images of the hollow viscera being extracted by the extracting means based on the notable region being set by the notable region setting means (Col. 9, lines 14-18), and wherein the lesion detecting means detects the existence of the lesion of the organ region based on the deformation degree of the cross-sectional images of the hollow viscera being created by the creating means (Col. 19, lines 13-16).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to include in the method as outlined by Giger to include a

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means for extracting the hollow viscera out of the organ region being set by the organ region setting means; a notable region setting means for setting the notable region of the hollow viscera being extracted by the extracting means; and a means for creating the cross-sectional images of the hollow viscera being extracted by the extracting means based on the notable region being set by the notable region setting means, and wherein the lesion detecting means detects the existence of the lesion of the organ region based on the deformation degree of the cross-sectional images of the hollow viscera being created by the creating means, in order to facilitate the examination of other internal organs other than a mammary, as Giger specifically details.

22. **Regarding claims 7 and 17,** Giger discloses all the limitations of claims 6 and 16, upon which claims 7 and 17 are dependent. Giger also discloses a visual presentation that highlights the lesion candidate portions being detected by the lesion detecting means on the images (Claim 4), but fails to disclose the visual presentation to the examiner being executed by displaying cross-sectional images.

Greenberg discloses visually presenting cross-sectional images to an examiner (Claim 11: means for expressing the X-ray intensity for each X-ray image as lumen functions across an artery cross section).

Incorporating the teachings of Greenberg, allows for discriminating the details of the region of interest in such a way that would facilitate identification of lesions of other organs other than mammarys in Giger's method. Lesions and stenosis of organs have geometric characteristics such as constriction that a cross-sectional

image would present in a more obvious manner. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to apply the teachings of Greenberg to Giger's methods.

23. **Regarding claims 9 and 19,** Giger discloses the limitations of claims 1 and 11, upon which claims 9 and 19 are dependent but fails to disclose the limitations of claim 9 and 19.

Greenberg discloses a cross-section extracting means for extracting the cross sections from the feature quantity of the hollow viscera on the tomographic images being obtained by the medical imaging device (Co1.5, lines 30-33: Greenberg does this using lumen functions.); a physical quantity calculating means for calculating the physical quantity including the radius, degree of circularity, and gravity point of the hollow viscera on the hollow viscera cross-sections being extracted by the extracting means (Col. 3, lines 19-25: analysis of a cross-sectional area could produce radius, degree of circularity as well as gravity point (understood to be a center point)) ; an ROI calculating means for calculating the region of interest based on the physical quantity being calculated by the physical quantity calculating means (col. 3, lines 26-30); a 3-dimensional image creating means for creating the 3-dimensional images of the hollow viscera from the tomographic images including the cross sections of the hollow viscera being extracted by the cross section extracting means within the region of interest being calculated by the ROI calculating means (Claim 1 :

reconstructing the lumen functions to create a three-dimensional image); and an image displaying means for displaying the 3-dimensional images being created by the 3-dimensional image creating means (Abstract: lines 7-8; see also Fig. 3A).

Incorporating the teachings of Greenberg, allows for analysis and display of results in a non-mammary thoracic examination in Giger's method. As Giger mentions, his methods of mammary examination can also be used to examine other thoracic elements as Greenberg's method does, using appropriate terms and methods. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to apply the teachings of Greenberg to Giger's methods.

Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger, in view of Heilbrun et al. (U.S. Pub. No.:20010039421 A1,"Heilbrun " and in further view of Mault (U.S. Pub. No.: 200110044588 A1,"Mault").

24. **Regarding claims 8 and 18,** Giger discloses all the limitations of claims 1 and 11, upon which these claims are dependent, as well as displaying the existence of a lesion to an examiner (Claim 4) but fails to disclose the presentation in a voice and sound format.

Heilbrun discloses notification by a computer in a voice format (Page 8, lines 6-10). While Heilbrun's notification is regarding the position the position of the operative portion of an instrument relative to structures of interest, it is the goal to

notify the operator of relevant information that is important. In Heilbrun's invention, the relevant information that needs to be related to the examiner is the position of the operative portion of an instrument, while in Giger's invention, the relevant information is the notification of the location of a lesion. Giving auditory notification to an operator of some type of event which is in the interest of the operator to notice is an obvious method that is used in many arts.

Mault discloses notification of a certain event using both display and sound (Paragraph [0016], lines 1-6). Notification by sound is an obvious variation of using voice alerts since voice is an organized set of sounds relating to speech, therefore, the use of voice in itself is the use of sound.

Incorporating the teachings of Heilbrun and Mault, allows for improving the notification of the location of a lesion to an examiner in Giger's method. Auditory notification, additional to any visual notification (as there is in Giger's invention: claim 4) would improve the efficiency of drawing an examiner's attention to the location of a lesion. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to apply the teachings of Heilbrun and Mault to Giger's methods.

Claims 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger, in view of Greenberg and in further view of Knoplioch (U.S. Patent Number: 6643533, "Knoplioch").

25. Regarding claims 10 and 20, while Giger and Greenberg disclose the limitations of claims 9 and 19, they fail to disclose the limitations of claims 10 and 20.

Knoplioch discloses a center-line calculating means for calculating the center line of the hollow viscera based on the gravity point of the hollow viscera cross sections being calculated by the physical quantity calculating means (Col. 6, lines 31-34), wherein the image display means displays the center line being calculated by the center-line calculating means together with the 3-dimensional images being created by the 3-dimensional image creating means (Col. 3, lines 22-24; with reference to Fig. 4 - See also: Col. 5, lines 18-23).

Incorporating the teachings of Knoplioch, allows for geometrical display of the organs under scrutiny with reference to a centerline which would facilitate critical analysis of any objects of interest in Giger and Greenberg's method. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to apply the teachings of Knoplioch to Giger and Greenberg's methods.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yoshitaka et al. (Region-Growing Based Feature Extraction Algorithm for Tree-Like Objects, Visualization in Biomedical Computing, Springer

BerlinlHeidelberg, Vol. 1 13111 996, copyright 1996, pages 159-1 71) discloses background information regarding region growing and describes it to be used for segmentation, using a seed point and categorizes it as a morphological operation called 'closed-space dilation', in other words, a bounded dilation operation (Section 2, paragraph 2). Matsugu et al. (US 6,167,167) discloses an image extraction method which segments background and foreground, shadow removal and region growing based on characteristics of neighboring pixels.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THOMAS A. CONWAY whose telephone number is (571)270-5851. The examiner can normally be reached on Monday through Friday 8AM - 5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Benny Tieu can be reached on 571-272-7490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-21 7-91 97 (toll-free). If you would like

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assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas A. Conway/
Examiner, Art Unit 4182

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